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Hinshon et al.

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(54) **ADJUSTABLE LUMBO-SACRAL ORTHOSIS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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Related U.S. Application Data

(63) Continuation of application No. 13/632,880, filed on Oct. 1, 2012, now Pat. No. 8,920,353, which is a (Continued)

(51) **Int. Cl.**
A61F 5/02 (2006.01)

(52) **U.S. Cl.**
CPC **A61F 5/028** (2013.01)

(58) **Field of Classification Search**
CPC A61F 13/15764; A61F 13/15699; A61F 13/49011; A61F 5/028; A61F 13/15593; A61F 13/15739; A61F 13/15577; A61F

13/15804; A61F 13/496; A61F 13/4963; A61F 13/15585; A61F 13/15747; A61F 5/0102; A61F 5/0193; A61F 2250/001; A61F 5/024; A61F 5/32; A61F 5/34; A61F 5/026; A61F 5/03; A61F 13/14; A61F 5/0118; A61F 5/0111; A61F 5/0585; A61F 5/01; A61F 13/04; A61F 2250/006; A63B 21/023; A63B 21/0428; A63B 21/05; A63B 21/1419; A63B 21/1449; A63B 23/1245; A61H 2201/0103; A61H 2011/005; A61H 2031/003; A61H 2201/0176;

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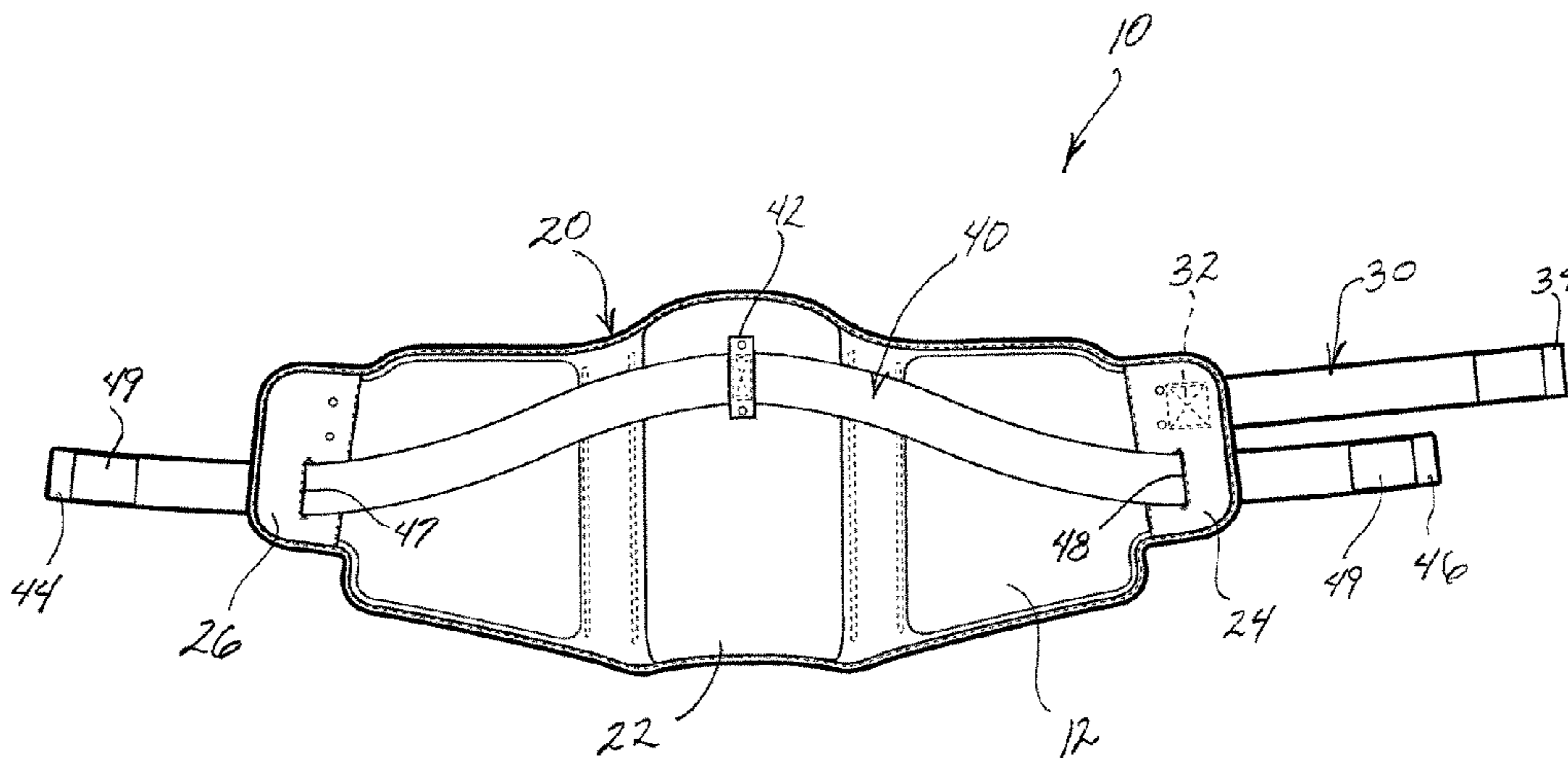
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(57) **ABSTRACT**

A lumbo-sacral orthosis having a main body member sized to wrap substantially around a body of a wearer at the wearer's lumbar and sacral region. An outer holds the main body member at the wearer's lumbar and sacral region. An inner belt is cinched to compresses the wearer's body at the waist groove. A lumbar panel with an independently movable flexible element may be supported by the main body member. Side panels may also be supported by the main body member along with an abdominal panel which may include an independently movable lower element.

18 Claims, 8 Drawing Sheets



(Inside)

Related U.S. Application Data

continuation of application No. 13/472,882, filed on May 16, 2012, now abandoned.

- (60) Provisional application No. 61/611,669, filed on Mar. 16, 2012, provisional application No. 61/622,204, filed on Apr. 10, 2012, provisional application No. 61/486,438, filed on May 16, 2011.

(58) **Field of Classification Search**

CPC A61H 2201/018; A61H 2201/5007; A61H 2201/501; A61H 2201/5012; A61H 2201/5043; A61H 2201/5058; A61H 2201/5061

USPC 602/17-19; 2/336-338; 128/874-875
See application file for complete search history.

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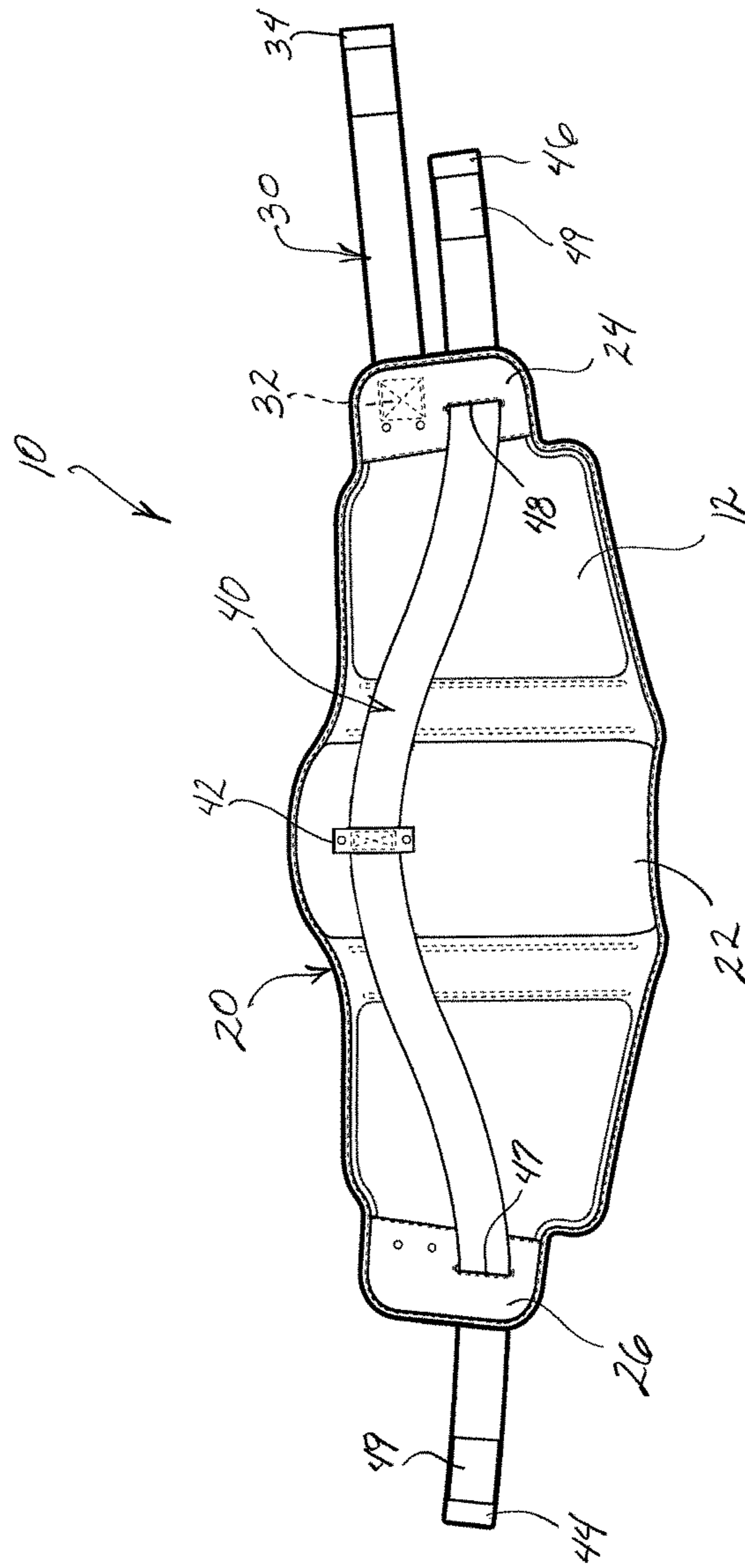


FIG. 1
(Inside)

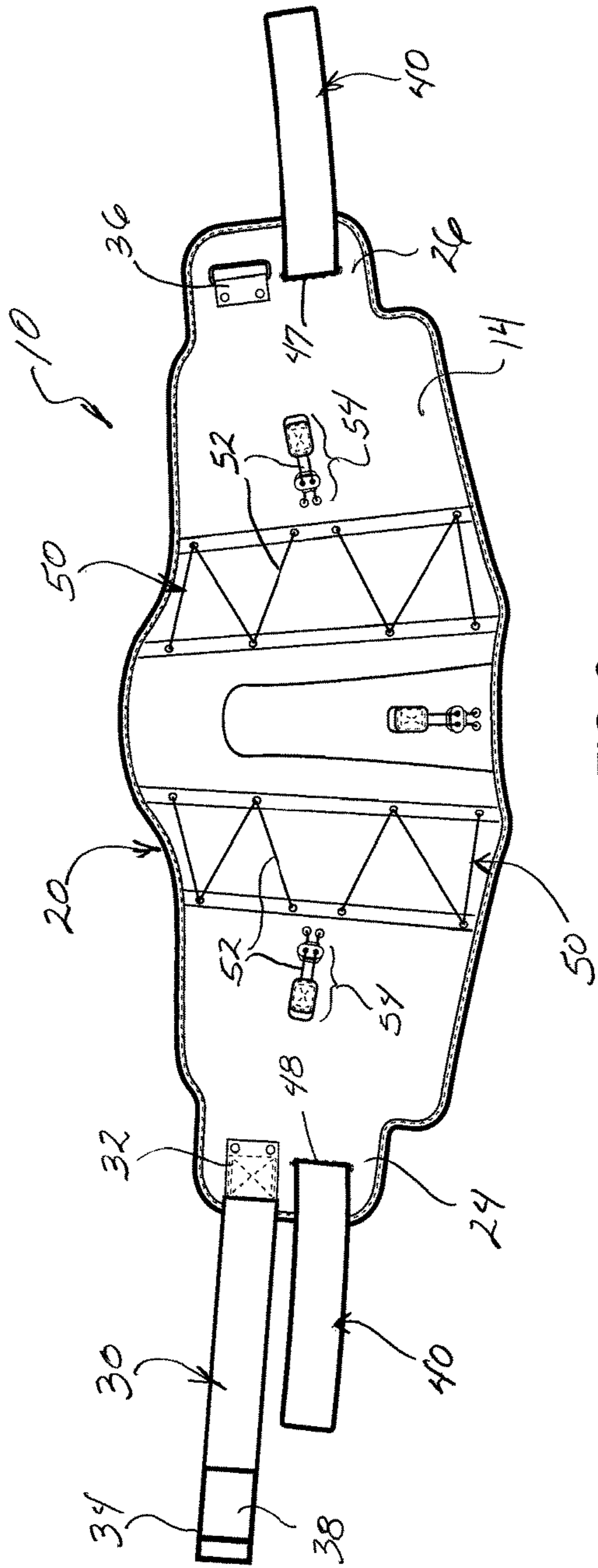


FIG. 2
(Outside)

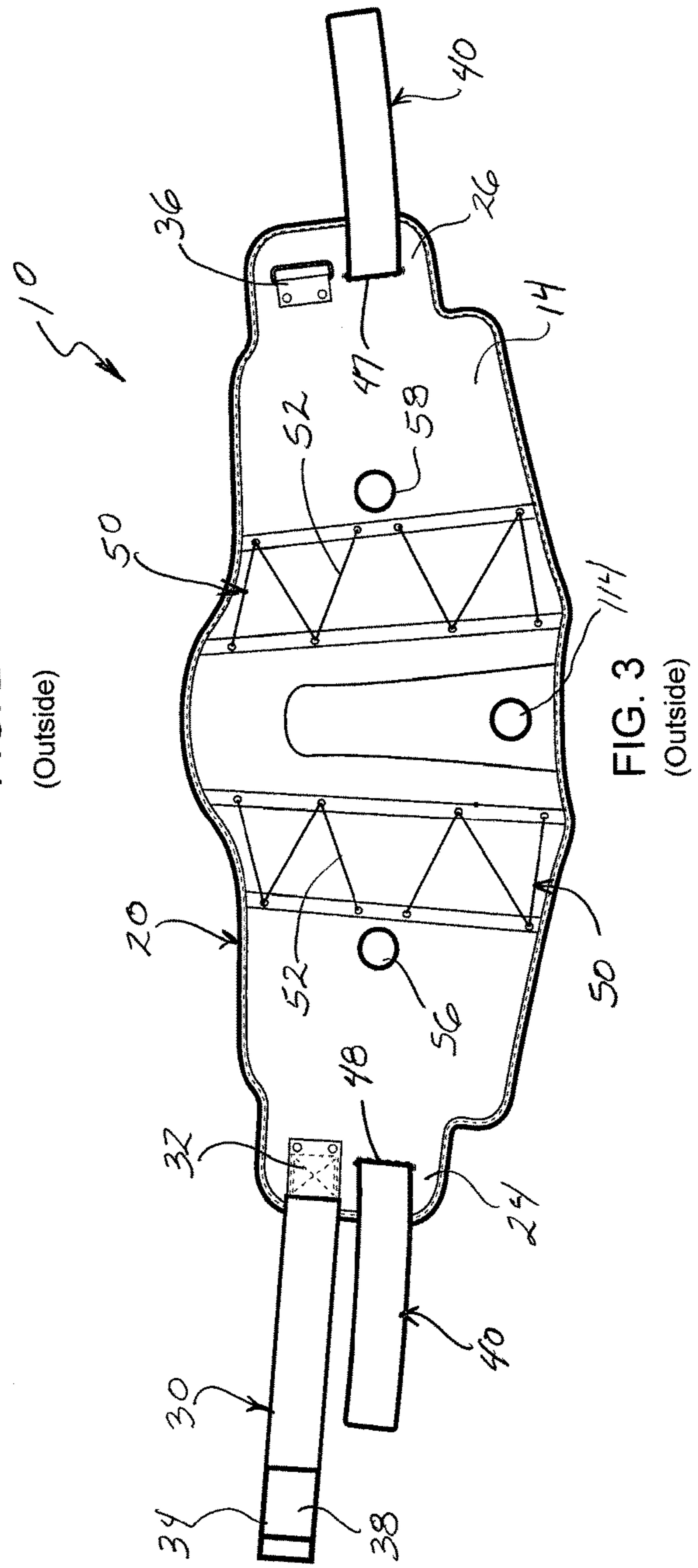


FIG. 3
(Outside)

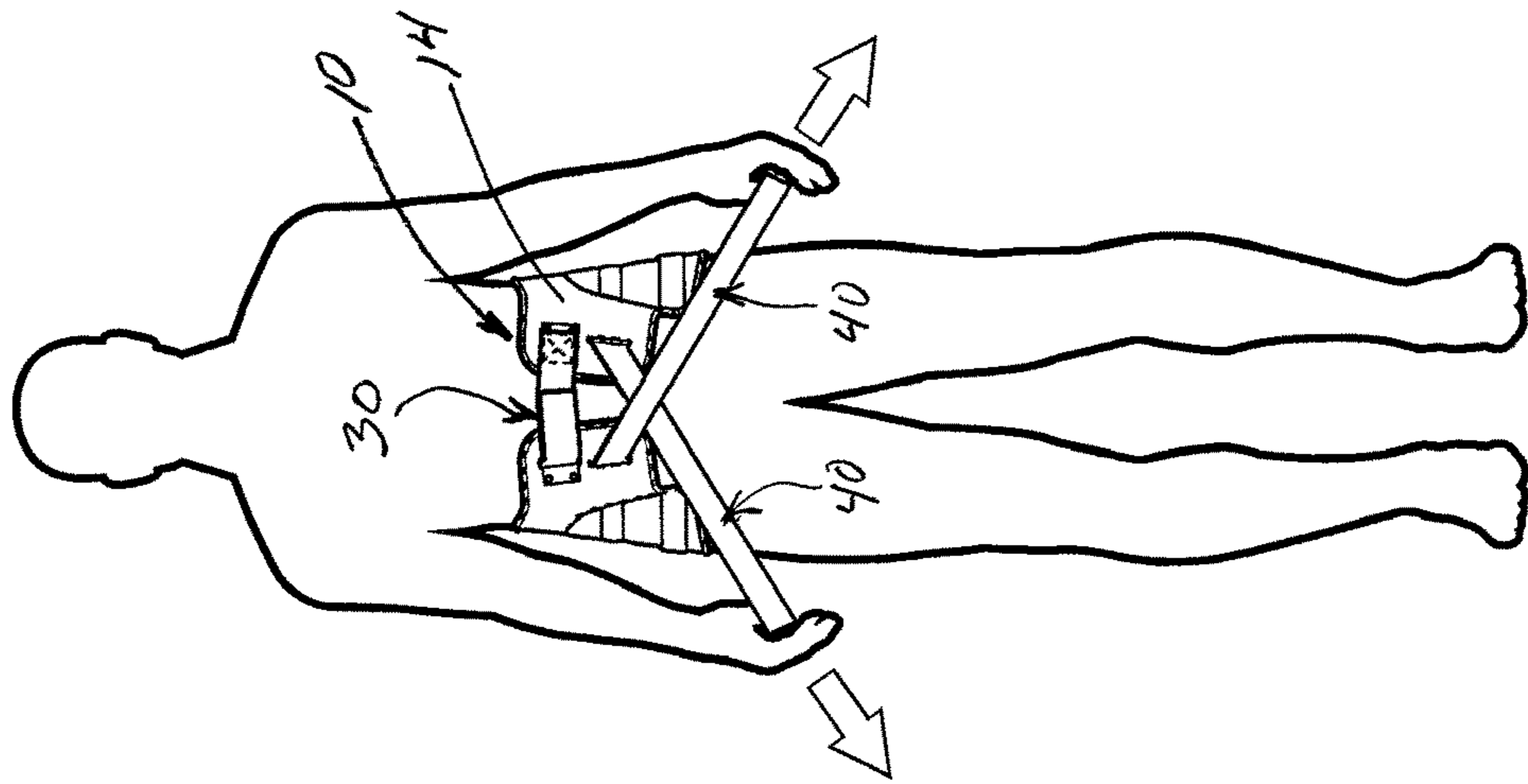


FIG. 4

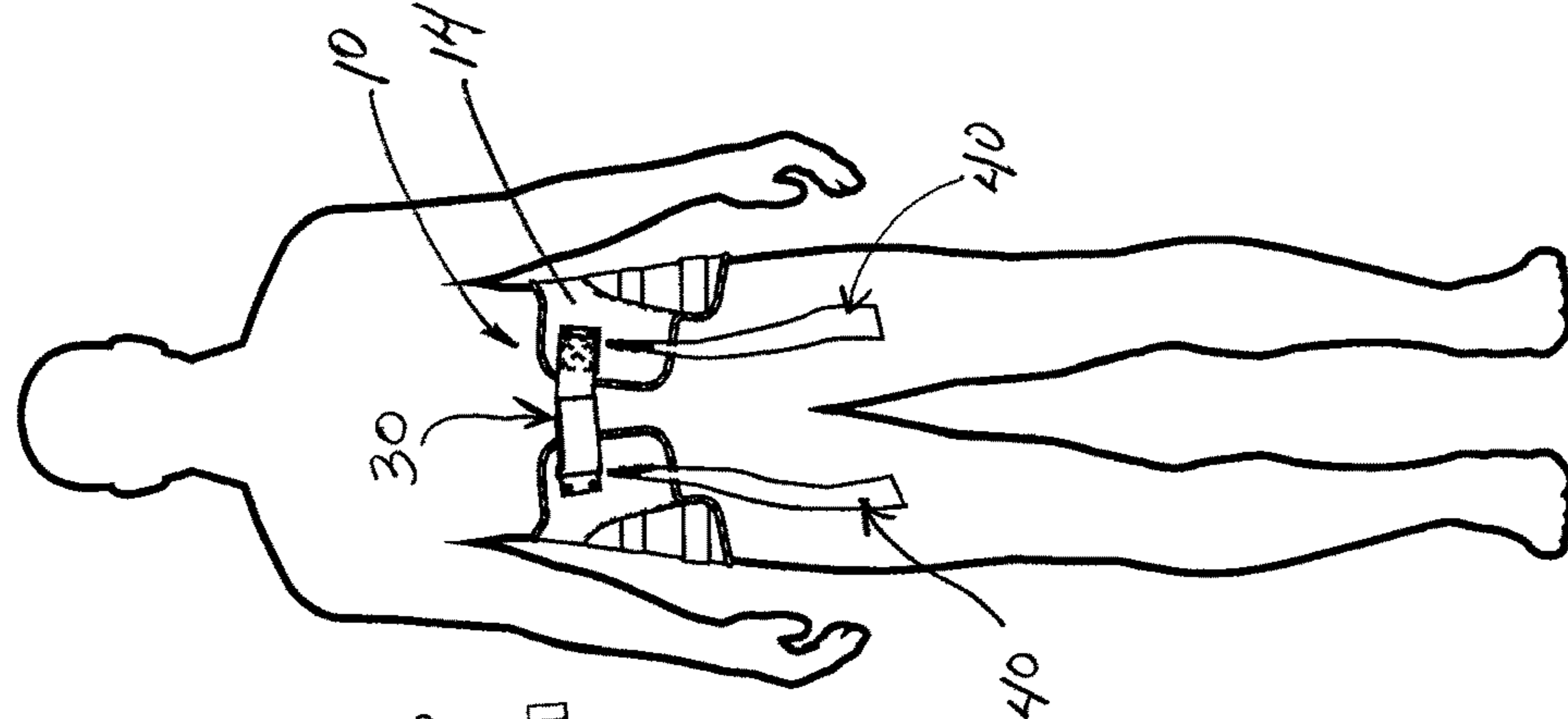


FIG. 5

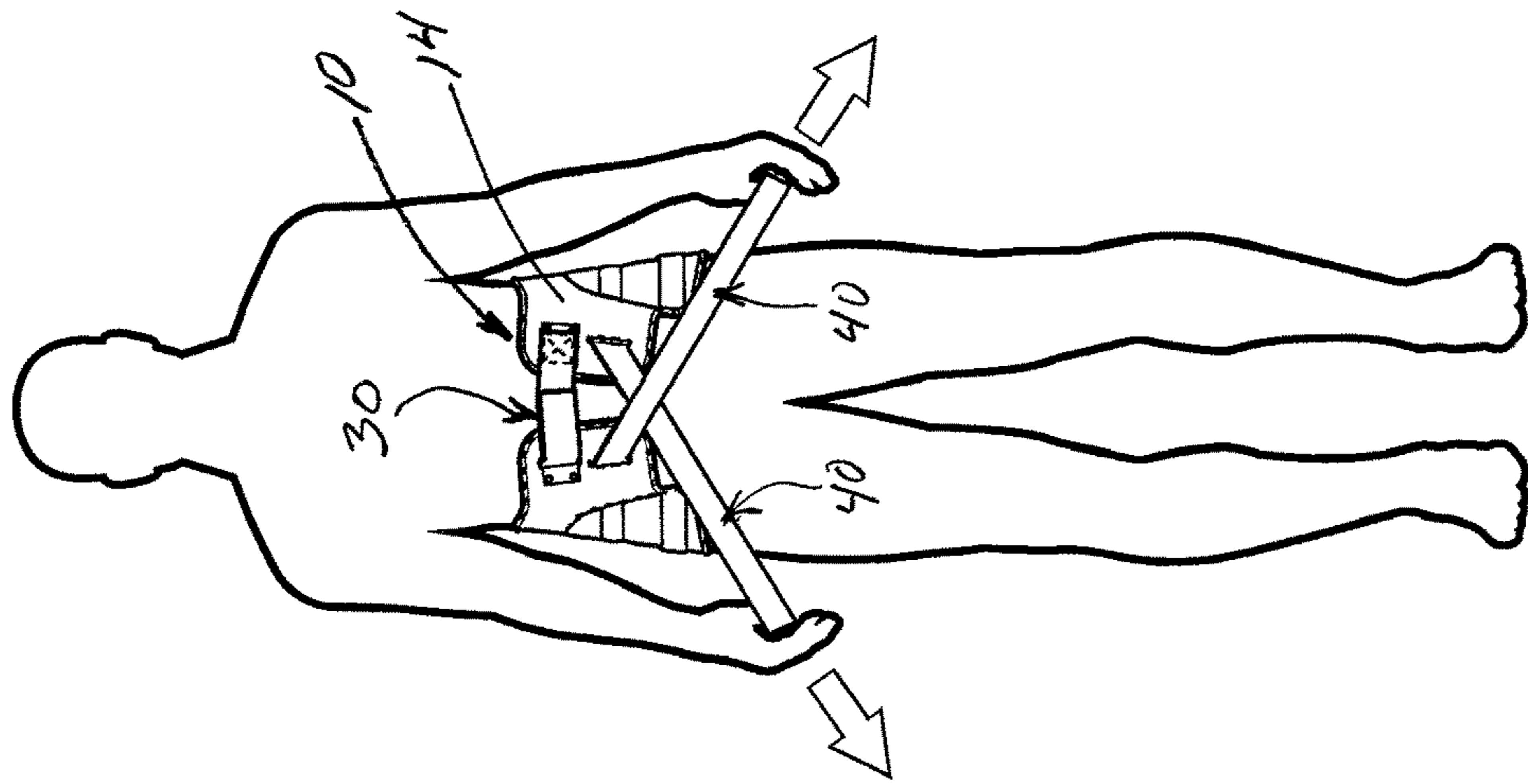


FIG. 6

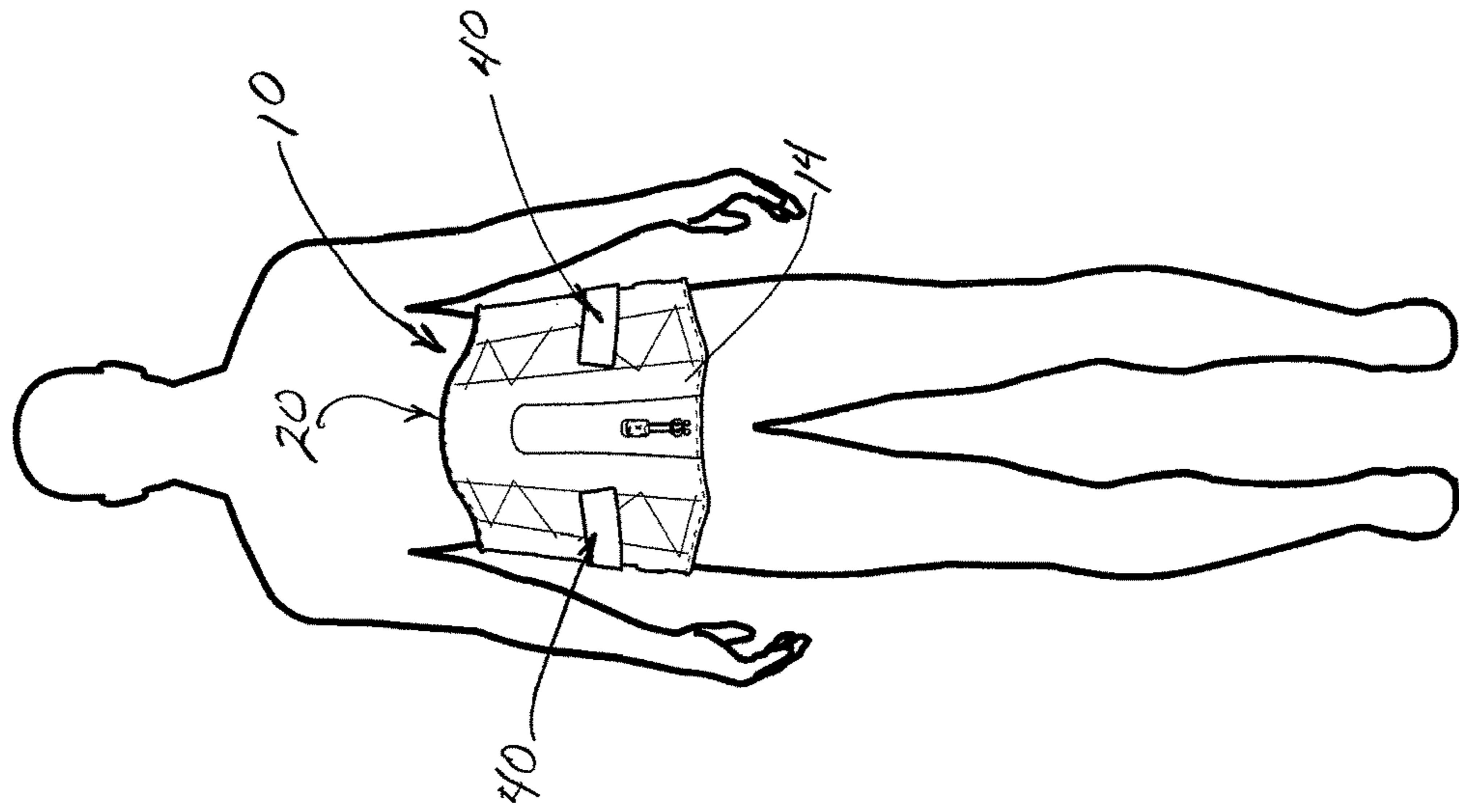


FIG. 8
(Back)

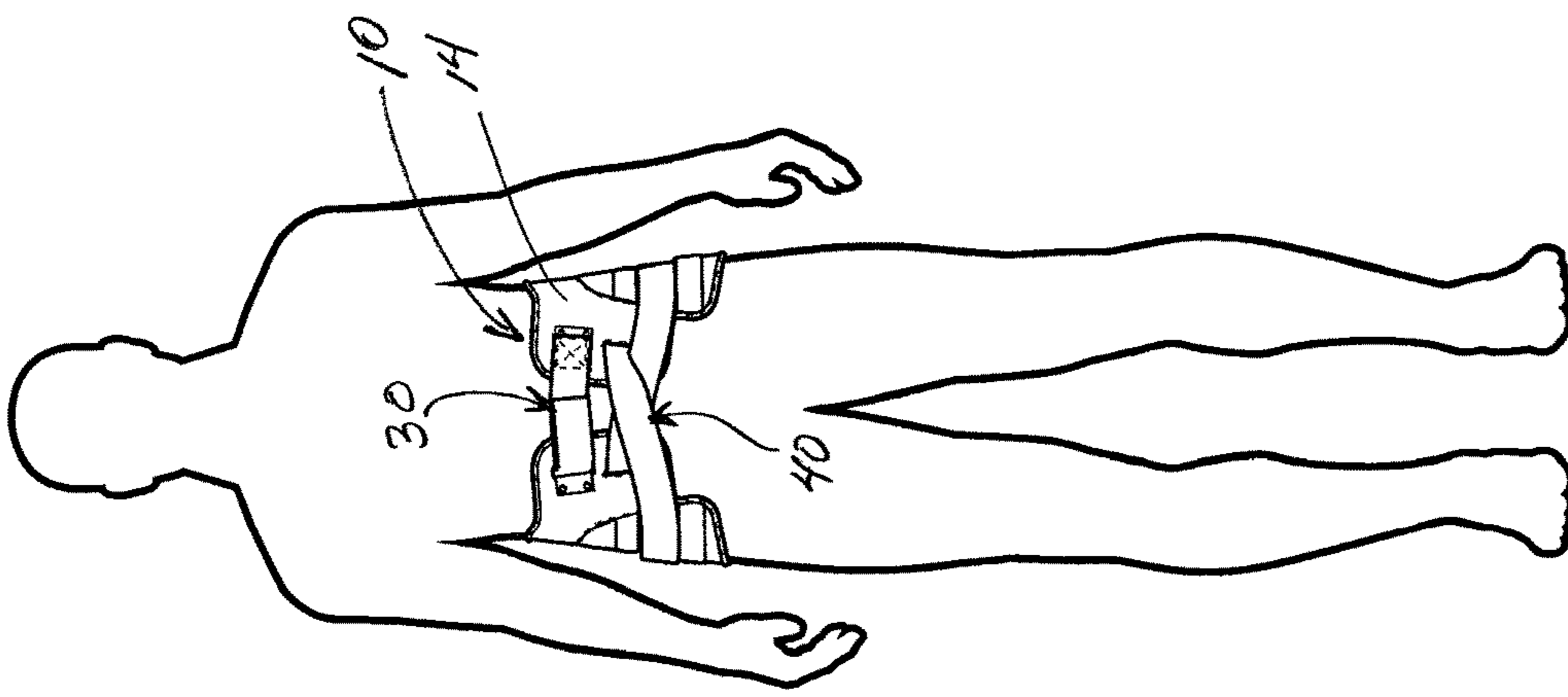


FIG. 7
(Front)

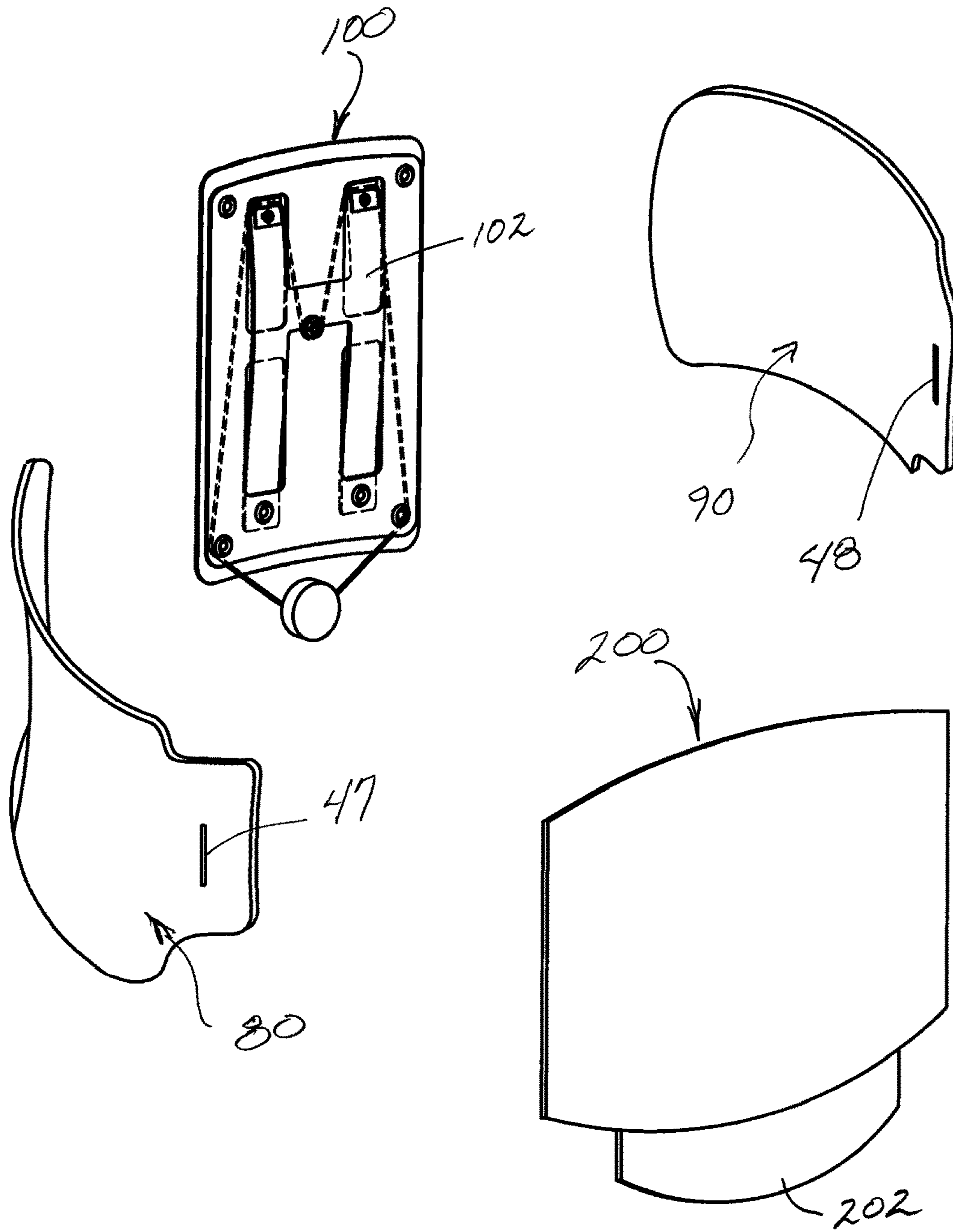


FIG. 10

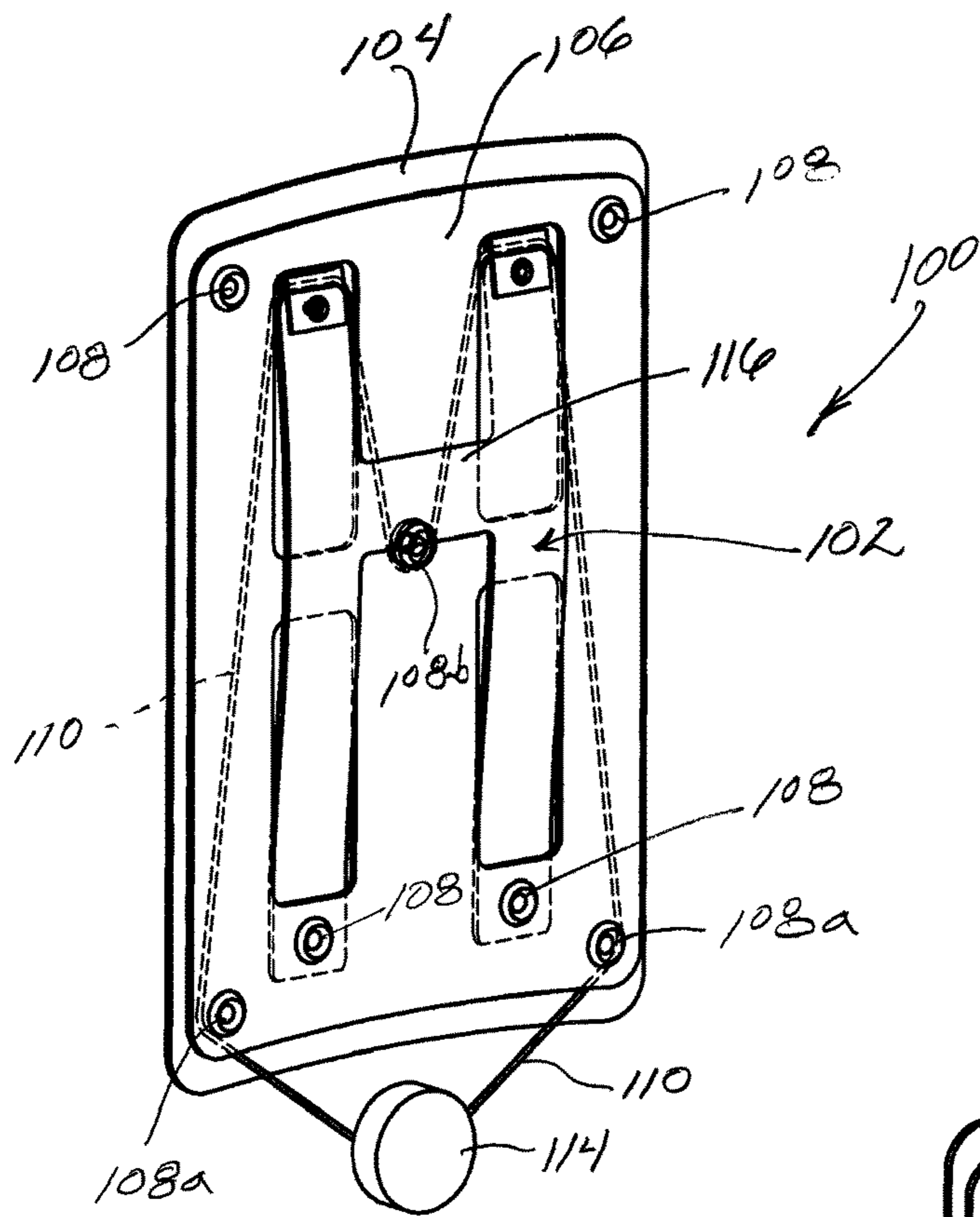


FIG. 11

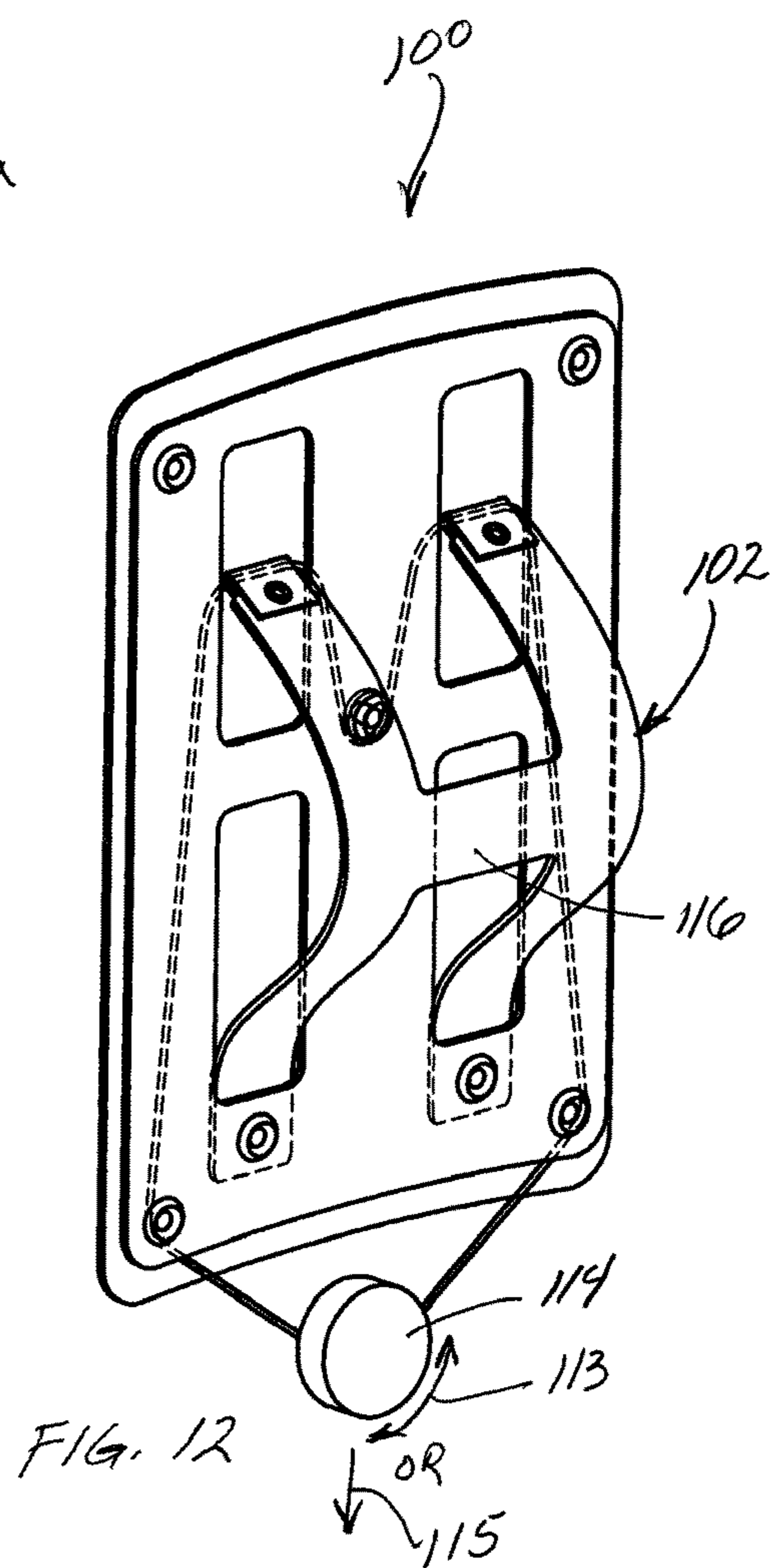


FIG. 12

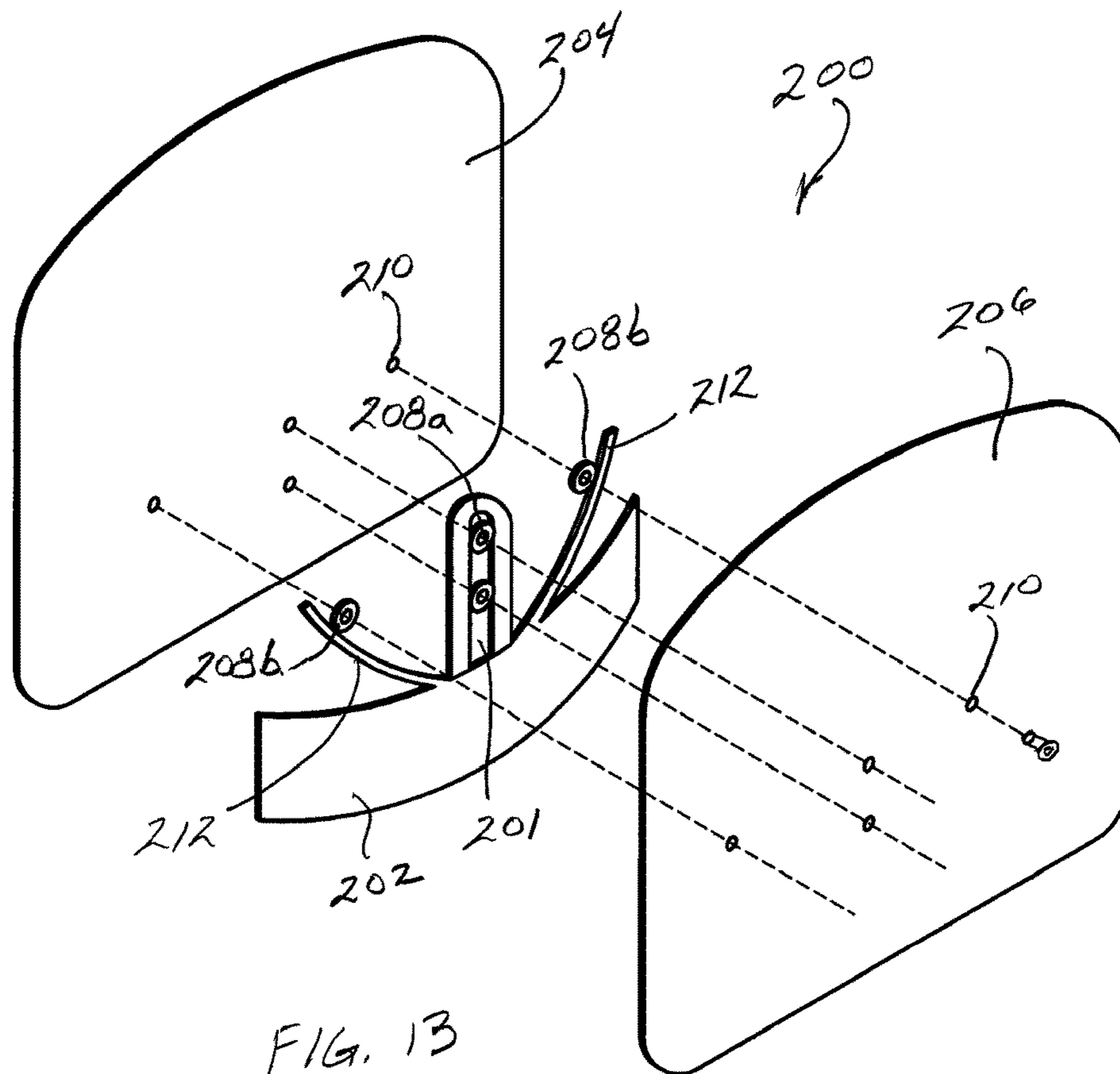


FIG. 13

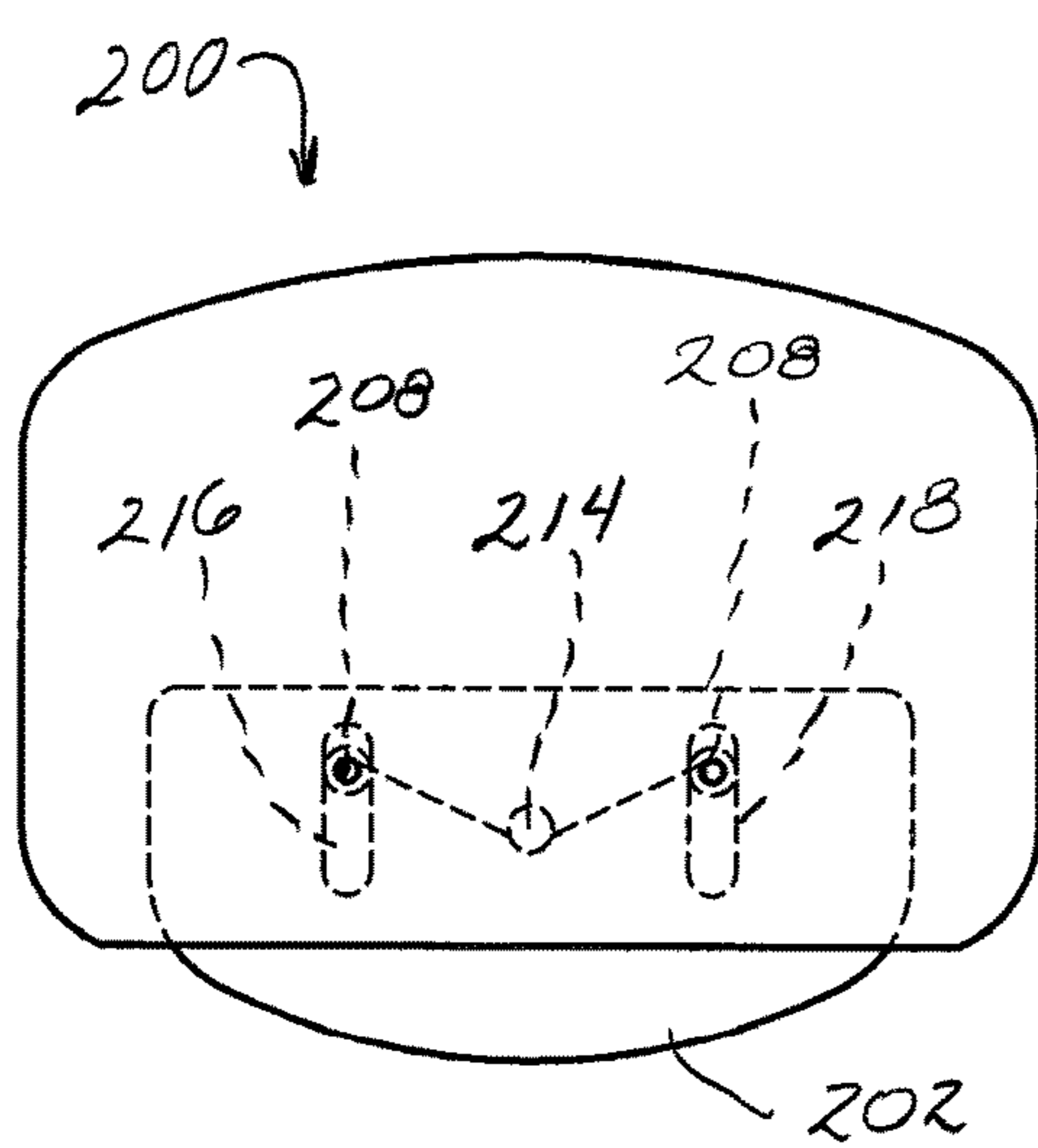


FIG. 14

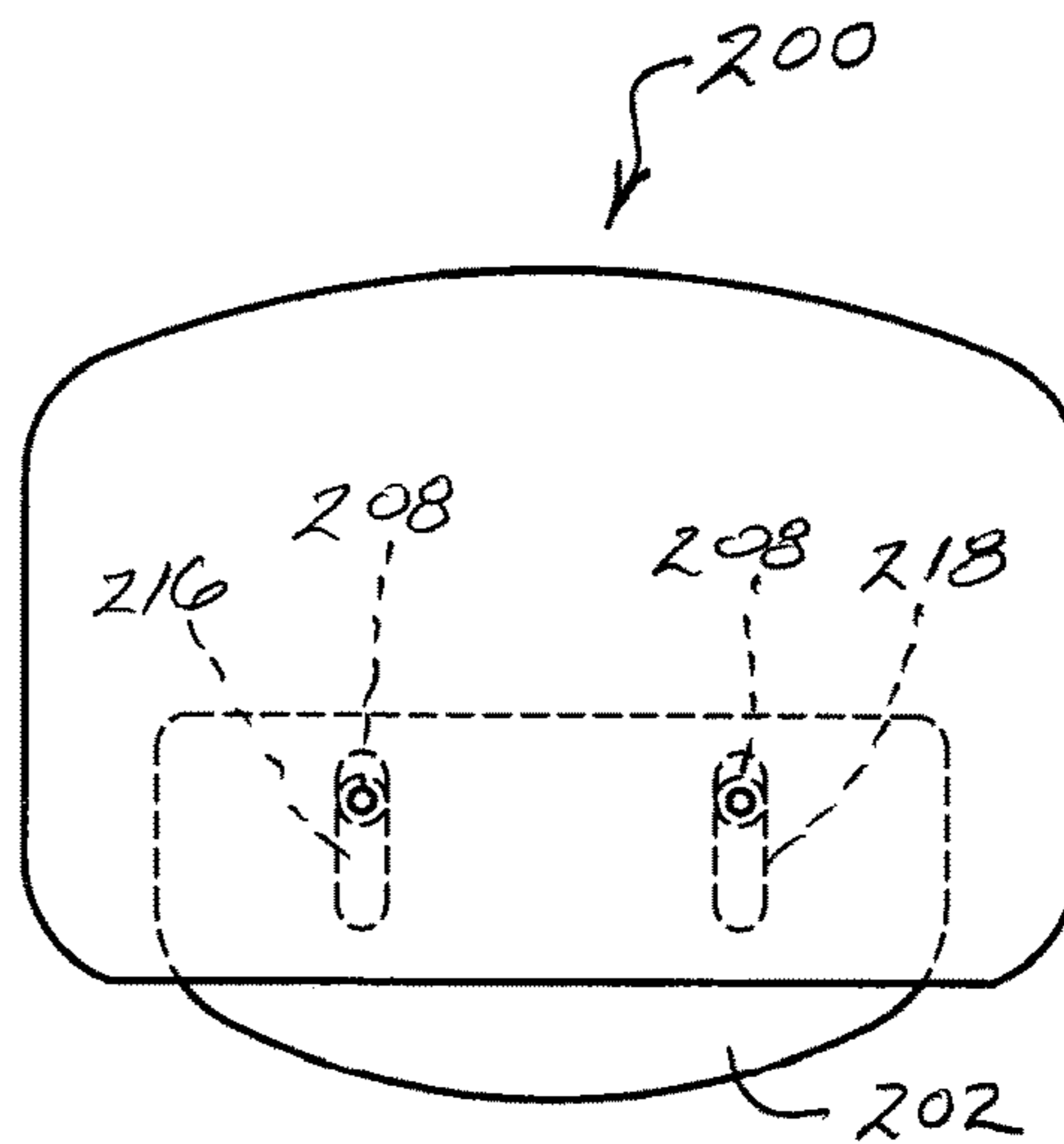


FIG. 15

ADJUSTABLE LUMBO-SACRAL ORTHOSIS

CROSS-REFERENCE TO RELATED APPLICATIONS

This is a continuation of U.S. patent application Ser. No. 13/632,880, filed Oct. 1, 2012, which is a continuation-in-part application of U.S. patent application Ser. No. 13/472,882 filed May 16, 2012 which claims priority to U.S. Provisional Application No. 61/486,438, filed May 16, 2011 and U.S. Provisional Application No. 61/611,669, filed Mar. 16, 2012, and U.S. Provisional Application No. 61/622,204, filed Apr. 10, 2012.

BACKGROUND

There are various types of commercially available orthoses that are intended for stabilizing and immobilizing the lumbar and sacral region of the body for the treatment of low back pain due to lumbar sprain, spinal stenosis, disc herniation, and different degenerative spinal disorders. However, presently available lumbo-sacral orthosis suffer from one or more shortcomings or deficiencies.

No two human bodies are the same. Even among individuals with similar weight and body types, a lumbo-sacral orthosis that may serve one individual well, but may be ill fitting on another. Accordingly, there is a need for a lumbo-sacral orthosis that is easily adjustable to ensure a proper fit and to maintain substantial immobilization of the lumbar and sacral region of the wearer at all times, including while standing, sitting or walking.

Lumbo-sacral orthoses are typically prescribed by orthopedic doctors and fitted to patients by a fitting practitioner during an office visit to ensure a proper fit. However, if the patient removes the orthosis for bathing or other reasons, it is difficult for the patient to position and adjust the orthosis to achieve the same fit as when it was initially fitted by the fitting practitioner. Accordingly, there is a need for a lumbo-sacral orthosis which a wearer can replace after removal and achieve the same or substantially the same fit as when initially fitted by fitting practitioner.

Also, as a patient moves during the course of the day, commercially available lumbo-sacral orthosis tend to ride-up on the wearer when moving from standing position to a sitting position, particularly if the orthosis includes an abdominal panel. For example, when a wearer sits, the abdominal panel will often contact the wearer's lap causing the orthosis to be forced upwardly causing discomfort to the wearer. Additionally, when the wearer returns to a standing position, the orthosis may no longer be properly positioned and in full contact with the wearer's body. If the orthosis is not in full contact with the wearer's body, the wearer's lumbar and sacral region will not be properly supported or substantially immobilized, permitting the wearer to slouch causing further injury or delaying recovery. Accordingly, there is a need for an lumbo-sacral orthosis that will remain in place as the wearer moves throughout the day, remains comfortable and in full contact with the wearer's lumbar and sacral region and will permit the wearer to sit without causing the orthosis to be forced upwardly and out of proper position.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates one embodiment of a lumbo-sacral orthosis as viewed from the inside or body-contact side.

FIG. 2 illustrates one embodiment of a lumbo-sacral orthosis as viewed from the outside or exterior side.

FIG. 3 illustrates another embodiment of a lumbo-sacral orthosis as viewed from the outside or exterior side.

FIGS. 4-6 illustrate the steps for fitting lumbo-sacral orthosis of FIGS. 1 and 2 to a wearer.

FIG. 7 illustrates the lumbo-sacral orthosis of FIGS. 1 and 2 positioned on a wearer as viewed from the front.

FIG. 8 illustrates the lumbo-sacral orthosis of FIG. 7 positioned on a wearer as viewed from the back.

FIG. 9 is an exploded view of the lumbo-sacral orthosis of FIGS. 1 and 2.

FIG. 10 is a perspective view illustrating one embodiment of the rigid panels of the lumbo-sacral orthosis of FIGS. 1-2 with the fabric and belts removed.

FIG. 11 is a perspective view illustrating an embodiment of an adjustable lumbar panel shown in the flat position.

FIG. 12 is a perspective view illustrating the adjustable lumbar panel of FIG. 11 in the flexed position.

FIG. 13 is a perspective view of one embodiment of an abdominal panel.

FIG. 14 is a front elevation view of another embodiment of an abdominal panel.

FIG. 15 is a front elevation view of another embodiment of an abdominal panel.

DESCRIPTION

Referring now to the drawing figures, wherein like reference numerals designate the same or corresponding parts throughout the several views, FIG. 1 illustrates one embodiment of a lumbo-sacral orthosis 10 as viewed from the inside face or body-contact side 12. FIG. 2 illustrates one embodiment of the lumbo-sacral orthosis 10 as viewed from the outside face or exterior side 14. FIG. 3 illustrates another embodiment of a lumbo-sacral orthosis 10 as viewed from the outside face 14.

The orthosis 10 has a main body 20, an exterior belt 30 and an interior belt 40. The main body has a middle section 22 and opposing ends 24, 26 and is sized to wrap around the body of a wearer at the wearer's lumbar and sacral region (see FIGS. 4-8). The inside face 12 and the outside face 14 of the main body are preferably made of wear-resistant, non-stretch fabric. As shown in FIG. 2, the exterior belt 30 has one end 32 secured to the outside 14 of the main body 20 (FIG. 2) proximate one end 24. The free end 34 of the exterior belt 30 may be inserted through a buckle 36 on the opposing end 26 on the outside of the main body 20. The free end 34 of the exterior belt 30 may include Velcro® patch 38 for attaching to a mating Velcro® patch or the fabric on the outside face of the main body 20. When being fitted with the orthosis, the wearer preferably pulls the free end 34 of the exterior strap 30 so the inside face 12 of the main body 20 is tight around his or her midsection. The free end 34 is then secured by Velcro to the outside face holding the orthosis in the proper position as illustrated in FIG. 5.

Referring to FIGS. 1, 5 and 6, the interior belt 40 is secured to the inside face 12 of the main body 20 proximate its middle by a loop 42 (FIG. 1). Each of the free ends 44, 46 pass through slots 47, 48 near the opposing ends 24, 26 of the main body 20 such that the free ends 44, 46 extend outside the main body 20. The free ends 44, 46 may also include Velcro® patches 49 (FIG. 1) for attaching to mating Velcro patches or the fabric on the outside face 14 of the main body 20. Comparing FIGS. 5-6, after the exterior belt 30 is tightened and secured, the wearer then grasps the free ends (FIG. 6), pulling outwardly to cinch the inner belt 40

tightly around the wearer's waist-groove. The free ends **44**, **46** are then secured to the outside face **14** of the main body **20**. It should be appreciated that by tightening the inner belt **40**, it will cause inward circumferential compression around the wearer's body at the waist-groove. This circumferential compressive force tends to distract the spine and provides containment of the abdomen thereby aiding in the relief of back pain as the lumbar region is forced to stretch or extend. To further tighten the interior belt **40**, a reel-based ratchet tightener such as available from Boa Technologies, Inc. and disclosed in U.S. Pat. No. 8,091,182 (hereinafter a "Boa System"), may be incorporated and employed (not shown) to further pull and tighten the interior belt **40**.

Referring again to FIGS. **2** and **3**, lacing **50** may also be incorporated and employed to further tighten the main body **20** of the orthosis **10** around the midsection of the wearer. The lace cords **52** may be pulled and tightened by hand and then locked in place using a well known sliding lock mechanism **54** (see FIG. **2**) or by incorporating and employing a Boa System as illustrated in FIG. **3**, showing left and right reel-based ratchets **56**, **58** of the Boa System.

FIG. **9** is an exploded view showing the various components of the orthosis of FIGS. **1** and **2**. As shown, the orthosis **10** comprises several elements which are shown in stacked relation from the outside of the orthosis toward the inside of the orthosis. The outermost element is non-stretch fabric panel **60**; then inner, fabric reinforcing panels **62**, **64**, **66**; then a middle non-stretch fabric panel **68**; then left and right side rigid panels **80**, **90**, and a rigid lumbar panel **100**; then an interior stretch-fabric panel **70**; and then interior end, fabric reinforcing panels **72**, **74**. The optional rigid abdominal panel **200** is positioned over the wearer's abdomen after the main body **20** of the orthosis is in position around the wearer's waste with the outer belt **30** loosely holding the orthosis in place. The outer belt **30** and inner belt **40** are then tightened and cinched as previously described.

FIG. **10** is a perspective view showing the arrangement of the rigid panels with respect to one another within the orthosis **10** with the main body **20** and belts **30**, **40** removed for clarity. As previously identified, the rigid panels include the left and right rigid side panels **80**, **90** the rigid lumbar panel **100** and the rigid abdominal panel **200** with main body **20** and belts **30**, **40** removed for clarity.

Referring to FIGS. **9** and **10**, the left and right rigid side panels **80**, **90** may be any desired configuration, but are preferably designed to be enclosed within the main body **20** of the orthosis **10**. Slots **47**, **48** are formed in the side panels to permit the free ends of the inner belt **40** to pass through the panels **80**, **90** and extend to the outside of the main body **20**. The rigid side panels **80**, **90** are also preferably curved and contoured such that when the inner belt **40** is cinched tightly within the wearer's waist groove and the outer belt **30** is tightened, the side panels cooperate with the lumbar panel **100** and the optional abdominal panel **200** and the main body **20** of the orthosis **10** to substantially immobilize the lumbar and sacral regions of the wearer. Although the embodiment of FIG. **10** shows the rigid panels **80**, **90** and **100** as being separate non-attached elements, if desired, the rigid side panels **80**, **90** may be attached to the lumbar panel **100**. For example, the panels **80**, **90** and **100** may include ears that extend toward one another which may then be adjustably attached by mating Velcro® patches. Alternatively, the ears may be attached by removable pins or rivets extending through aligned holes in the mating ears. In yet another alternative embodiment, the side panels **80**, **90** may be movably attached to the lumbar panel **100** by providing a groove or channel in the rearward end of the side panels **80**,

90 which slidably receive outwardly extending tongues projecting from respective sides of the lumbar panel **100**. In such an embodiment, as the outer belt **30** and inner belt **40** are tightened, the projecting tongues would slide inwardly within the groove or channel in the adjacent side panels **80**, **90**.

FIGS. **11** and **12** illustrate an embodiment of the rigid lumbar panel **100** which includes a flexible element **102** that may be project inwardly as string or cord is pulled. The lumbar panel **100** includes a substantially planar but slightly curved or arched back wall **104** and a substantially planar but slightly curved or arched front wall **106**. Rivets **108** or other suitable connectors connect the front wall **106** to the back wall **104** with spacers (not shown) disposed therebetween. The spacers are of sufficient height to permit a sting or cord **110** to pass between the front and back walls. One end of the flexible element **102** is also restrained between the front and back walls by rivets **108**. The cord **110** passes around the lower spacers and rivets **108a** as illustrated, extends through loops **112** at the upper end of the flexible element **102** and around the centrally positioned spacer and rivet **108b**. The ends of the cord may be received in a reel-ratchet **114** of a Boa System (see embodiment of FIG. **3**). Alternatively, or the ends of the cord may be received by a sliding lock mechanism (see embodiment of FIG. **2**).

In use, a wearer would rotate the reel-ratchet **114** of the Boa System as indicated by arrow **113** in FIG. **12** or pull downwardly on the cord as indicated by arrow **115** causing the flexible element to bow inwardly toward the wearers lumbar region as illustrated in FIG. **12**. This independently movable flexible element **102** allows the wearer to adjust the lumbar panel to ensure and maintain full contact with the wearers body to further immobilize the lumbar and sacral region of the wearer. Although FIG. **12** shows the flexible element as being joined by a horizontal bar **116** such that the left and right sides of the flexible element move together, it may be desired to eliminate the horizontal bar **116** to permit the left and right sides of the flexible member **102** to bow out independently of each other. It should also be appreciated that separate cords may be provided such that the wearer may pull each cord to independently adjust the right and left sides of the flexible member. Likewise the flexible element **102** may be rotated **90** degrees such that the flexible members bows inwardly in a horizontal direction rather than vertically. In such an embodiment, the wearer would pull on the chords in a horizontal direction from the right and/or left sides. Alternatively, the flexible element may be rotated **180** degrees such that the wearer would pull upwardly (as opposed to downwardly as alternatively shown in FIG. **12**). Of course if a Boa System is utilized, the reel-ratchet could be placed anywhere on the orthosis for easy reach by the wearer and the orientation of the flexible element could be vertical or horizontal.

FIG. **13** illustrates an embodiment of an abdominal panel **200** which includes an independently movable lower element **202** that will retract vertically when the wearer of the orthosis **10** moves between standing and sitting positions as the lower element comes in contact with the wearers lap when he or she sits, but will return to the extended position when standing. In the embodiment of FIG. **13**, the abdominal panel **200** includes a back wall **204** and a front wall **206**. Rivets **108** or other suitable connectors connect the front wall **206** to the back wall **204** with spacers **208** disposed therebetween through aligned holes **210**. The spacers **208** are of sufficient height to permit the lower element **202** to move vertically between the front and back walls. Centrally located spacers **208a** are received within a vertical channel

5

201 of the movable lower element **202** to serve as guides such that the lower element will move substantially vertically between the front and back walls. Outer spacers **208b** are positioned to engage upwardly extending resilient biasing arms **212** which serve to biasing the movable lower element **202** in the extended position.

FIG. **14** is an alternative embodiment of the abdominal panel **200**. Rather than utilizing biasing arms **212** as in the previous embodiment, a torsion spring **214** is utilized to bias the lower element **202** downwardly. In this embodiment the lower element includes two channels **216**, **218** which receive spacers **208** to vertically guide the lower element **202**.

FIG. **15** is yet another alternative embodiment of the abdominal panel **200** which is substantially identical to the embodiment of FIG. **14**, but without the torsion spring or any other biasing element.

The foregoing description is presented to enable one of ordinary skill in the art to make and use the invention and is provided in the context of a patent application and its requirements. Various modifications to the preferred embodiment of the apparatus, and the general principles and features of the system and methods described herein will be readily apparent to those of skill in the art. Thus, the present invention is not to be limited to the embodiments of the apparatus, system and methods described above and illustrated in the drawing figures, but is to be accorded the widest scope consistent with the spirit and scope of the appended claims.

The invention claimed is:

1. A lumbo-sacral orthosis, comprising:
 - (a) a main body member having an inside face, an outside face, a middle section, and first and second ends, said main body member having a length sized so as to be capable of wrapping substantially around a body of a wearer at the wearer's lumbar and sacral region;
 - (b) an outer belt having a length and a first end, the first end directly attached to said first side of said main body member, said length fastenable to said second end of said main body member so as to hold said main body member at the wearer's lumbar and sacral region with said inside face of said main body member adjacent the wearer's body;
 - (c) an inner belt having a length extending along a majority of said length of said main body member and disposed adjacent said middle section of said main body member, said inner belt configured so that it is capable of being cinched independently of said main body member and such that, when cinched, said interior length of said inner belt is in contact with said wearer's lumbar region and said waist groove causing compression substantially around said wearer's body at said wearer's lumbar region and waist groove.
2. The lumbo-sacral orthosis of claim 1, further comprising:
 - a rigid lumbar panel disposed between said inside face and said outside face of said main body member at said middle section.
3. The lumbo sacral orthosis of claim 2 wherein said rigid lumbar panel includes a rigid wall and a flexible element movable independently of said rigid wall between a flat position and an inward bowed position.
4. The lumbo sacral orthosis of claim 3 further including a cord which when pulled, causes said flexible element to move from said flat position to said inward bowed position.
5. The lumbo sacral orthosis of claim 4 further including a rotatable reel-based ratchet which when rotated pulls said

6

cord to cause said flexible element to move from said flat position to said inward bowed position.

6. The lumbo-sacral orthosis of claim 2, further comprising:

- a first rigid side panel disposed between said inside face and said outside face of said main body member and between said middle section and said first end of said main body member; and
- a second rigid side panel disposed between said inside face and said outside face of said main body member and between said middle section and said second end of said main body member.

7. The lumbo-sacral orthosis of claim 1 further comprising a rigid abdominal panel, said rigid abdominal panel disposed adjacent the wearer's abdomen interiorly of said inside face of said main body member when said main body member is wrapped around the body of the wearer.

8. The lumbo-sacral orthosis of claim 7 wherein said rigid abdominal panel, includes a rigid wall and a lower element vertically movable independently of said rigid wall between an extended position and a retracted position.

9. The lumbo-sacral orthosis of claim 8 wherein said lower element is biased in a direction toward said extended position.

10. The lumbo-sacral orthosis of claim 1, wherein said inner belt includes:

- a first end passing through said main body member proximate said first end of said main body member and extending exteriorly from said outside face; and
- a second end passing through said main body member proximate said second end of said main body member and extending exteriorly from said outside face.

11. A method of supporting and substantially immobilizing the lumbar and sacral regions of an individual, comprising:

- (a) wrapping a main body member substantially around the individual's body at the individual's lumbar and sacral region, said main body member having an inside face, an outside face, a middle section, and first and second ends;
- (b) fastening an outer belt to said second end of said main body member to hold said main body member at the individual's lumbar and sacral region with said inside face of said main body member adjacent the individual's body, said outer belt directly attached to said first end of said body member;
- (c) cinching an inner belt to compress the individual's body at the individual's waist groove, said inner belt having a length disposed adjacent said middle section of said main body member, whereby, when cinched, said interior length of said inner belt is in contact with said wearer's lumbar region and waist groove causing compression substantially around said wearer's body at said wearer's lumbar region and waist groove.

12. The method of claim 11, wherein said main body member has a length, said inner belt having a length extending along a majority of said length of said main body member.

13. The method of claim 12 wherein said main body member supports a rigid lumbar panel disposed between said inside face and said outside face of said main body member at said middle section.

14. The method of claim 13 wherein said rigid lumbar panel includes a rigid wall and a flexible element movable independently of said rigid wall between a flat position and an inward bowed position.

15. The method of claim 14 further comprising:
pulling a cord to cause said flexible element to move from
said flat position to said inward bowed position.

16. The method of claim 15 wherein the step of pulling
said cord includes rotating rotatable reel-based ratchet to 5
cause said flexible element to move from said flat position
to said inward bowed position.

17. The method of claim 13 wherein said main body
member further supports a first rigid side panel disposed
between said inside face and said outside face of said main 10
body member and between said middle section and said first
end of said main body member, and a second rigid side panel
disposed between said inside face and said outside face of
said main body member and between said middle section
and said second end of said main body member. 15

18. The method of claim 12 wherein said inner belt
includes:

- a first end passing through said main body member
proximate said first end of said main body member and
extending exteriorly from said outside face; and 20
- a second end passing through said main body member
proximate said second end of said main body member
and extending exteriorly from said outside face.

* * * * *